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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,782	09/15/2003	Marjorie L. Wier	04200001CB	7256
30743	7590	02/21/2006	EXAMINER	
WHITHAM, CURTIS & CHRISTOFFERSON, P.C. 11491 SUNSET HILLS ROAD SUITE 340 RESTON, VA 20190			CHEN, STACY BROWN	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/661,782	WIER, MARJORIE L.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 32-47 is/are pending in the application.
- 4a) Of the above claim(s) 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/15/03</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's election without traverse of Group II, claims 33-47, received December 7, 2005 is acknowledged. Claims 32-47 are pending. Claims 33-47 are under examination. Claim 32 is withdrawn from consideration being drawn to a non-elected invention.

#### ***Specification***

2. The specification as originally filed is objected to because the first line of the first page of the specification does not reference related applications to which the instant application claims priority. Specifically, USSN 09/059,573, now US patent 6,630,316, and USSN 08/928,392; now US patent 5,773,232, should be cited.

#### ***Claim Objections***

3. Claim 46 is objected to because of the following informalities: "wherein said control sample is liposomes containing ATP", should be corrected for appropriate grammar.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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- With regard to claims 33, 34 and all respective dependent claims, the method steps are incomplete. While all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The minimum requirements for method steps minimally include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or visualized, and a correlation step describing how the results of the assay allow for the determination. In this instance, the method for detecting activation of lymphocytes is accomplished by determining activation of lymphocytes (see claim 33, line 10, for example. There must be a correlation step that links the method steps back to the preamble. For example, how does measuring ATP levels (control and experimental) determine activation of lymphocytes?
- With regard to claim 33 and all dependent claims, the format of the method steps is unclear. In claim 33, there are clear steps of incubation, separation, lysis and measurement. The remaining steps appear to be a series of optional (“wherein”) details of carrying out the steps of separation, incubation and measurement. This format is not clear and should be amended. The format of dependent claim 34, for example, is an appropriate format for claiming details related to various steps of the method. Including all of the details in the alternative in the independent claim does not clearly set forth the subject matter of the claims.

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- References to “derived from” are unclear because the resulting “derived” products have not been assigned any core structure that remains from the original source. For example, claim 33 refers to “proteins derived from transplanted organisms”, which does not convey what the proteins actually are. Suggested language is, “proteins from transplanted organisms”. Further, it is unclear what a transplanted organism is.

### *Double Patenting*

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 47 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 5 of prior U.S. Patent No. 6,630,316 B1. This is a double patenting rejection.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re*

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*Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 33-46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,630,316. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed method of detecting activation of lymphocytes comprises the same steps of detecting activation of lymphocytes in the patented claims. The difference between the instant claims and patented claims is that the instant claims include further details of the method steps that were not previously claimed. For example, the patented claims are drawn to a method for detecting activation of lymphocytes utilizing an inducing agent selected from the group consisting of mitogens and antigens, specifically viruses, bacteria or fungi. The instant claims recite specific viruses, bacteria, and other agents such as organic chemicals, inorganic chemicals, metals, tumor cell proteins and proteins from transplanted organisms.

The specific embodiments instantly claimed are a species of the patented genus. A genus does not necessarily anticipate a species, however in this case, the specific viruses, bacteria and other inducing agents could have been claimed in the parent application. To the examiner's knowledge, a restriction requirement between the various viruses, bacteria, fungi, and other inducing agents was not set forth in the parent

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application, though the species were disclosed in the parent application. The inventive concept of the two claim sets is clearly the same, the only difference being specific organisms not recited in the patented claims.

7. Claims 33-47 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 5,773,232. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed method of detecting activation of lymphocytes comprises the same steps of detecting activation of lymphocytes in the patented claims. The patented claims are a species of the instantly claimed genus. The patented method claims are drawn to a method for “rapidly analyzing lymphocytes for lymphocyte activation” wherein the method is complete within 6-24 hours. While the instant claims do not recite any language relating to rapid analysis, the inventive concept of the two claim sets is the same. The different preambles of the patented claims (rapid analysis of lymphocyte activation) do not present a patentably distinct invention from the instant method claims (generic analysis of lymphocyte activation) because the actual method steps are the same, thus the outcomes are the same.

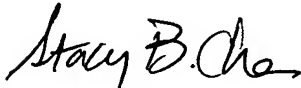
### *Conclusion*

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

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more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

A handwritten signature in black ink, appearing to read "Stacy B. Chen". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Stacy B. Chen  
February 17, 2006